

UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,668	03/01/2002	Edward L. Blach	12460.4USC1	8126
23552 7	590 10/28/2003		EXAMI	NER
MERCHANT & GOULD PC			DAWSON, GLENN K	
P.O. BOX 2903	3			
MINNEAPOLIS, MN 55402-0903			ART UNIT	PAPER NUMBER
			3761	
			DATE MAILED: 10/28/2003	10

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
Office Action Summary		10/087,668					
		Examiner	Art Unit				
		Glenn K Dawson	3761				
T	The MAILING DATE of this communication appears on the cover sheet with the correspondence address						
A SHOR THE MAI - Extension after SIX (- If the peri - If NO peri - Failure to - Any reply	TENED STATUTORY PERIOD FOR REPLING DATE OF THIS COMMUNICATION softime may be available under the provisions of 37 CFR 1 (6) MONTHS from the mailing date of this communication. Of for reply specified above is less than thirty (30) days, a record for reply is specified above, the maximum statutory perior reply within the set or extended period for reply will, by statureceived by the Office later than three months after the mailing tent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a reply be ply within the statutory minimum of thirty (30) o d will apply and will expire SIX (6) MONTHS fro tte, cause the application to become ABANDO	timely filed days will be considered timely. om the mailing date of this communication. NED (35 U.S.C. § 133).				
1)⊠ R	esponsive to communication(s) filed on 18	B August 2003 .					
	· · · · · · · · · · · · · · · · · · ·	This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition							
•	aim(s) <u>22-40</u> is/are pending in the applicat						
	4a) Of the above claim(s) is/are withdrawn from consideration.						
· —	5) Claim(s) is/are allowed.						
·	6)⊠ Claim(s) <u>22,25,26 and 28-40</u> is/are rejected.						
7)⊠ Cla	aim(s) 23,24 and 27 is/are objected to.						
	nim(s) are subject to restriction and/	or election requirement.					
Application	•						
· · · ·	specification is objected to by the Examin	<u></u>					
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12)☐ The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
1.[1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No							
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
2) D Notice of	References Cited (PTO-892) Draftsperson's Patent Drawing Review (PTO-948) on Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informa	ary (PTO-413) Paper No(s) al Patent Application (PTO-152)				

Application/Control Number: 10/087,668

Art Unit: 3761

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

Application/Control Number: 10/087,668

Art Unit: 3761

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22,25,26 and 28-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over lerulli-6453901 in view of Muchin-5718224 and either Heinecke-5088483 or Faasse-4744355.

lerulli discloses the device as claimed including a nasal dilator having a release liner 60, a support layer 12 positioned between an engaging layer 14 and a surface layer 22. However, the release liner has only two portions instead of 3.

However, the examiner contends that providing three release liner portions instead of 2 is nothing more than a mere duplication of known parts.

B. Duplication of Parts

In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) (Claims at issue were directed to a water-tight masonry structure wherein a water seal of flexible material fills the joints which form between adjacent pours of concrete. The claimed water seal has a "web" which lies ** in the joint, and a plurality of "ribs" ** >projecting outwardly from each side of the web into one of the adjacent concrete slabs. <The prior art disclosed a flexible water stop for preventing passage of water between masses of concrete in the shape of a plus sign (+). Although the reference did not disclose a plurality of ribs, the

court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced.).

Muchin discloses that it was known to apply the central portion of the dilator to the nose first before the lateral side portions.

Heinecke discloses an adhesive wound covering having as shown in fig. 2 a release liner of three components- a middle component 22, and two lateral components 24. In use, the middle component 22 is first removed from the covering, the adhesive which was protected by the central liner portion is pressed against the skin, the covering can then be properly positioned and then the lateral liner sections 24 can be peeled to expose lateral adhesive sections on the covering to be applied to spaced lateral locations around the wound.

Faasse discloses a wound covering having a release liner with actually two (2) central portions 30 and two lateral portions 20. Again, the central portions are removed thus exposing adhesive on the covering which is applied to the skin, the covering is properly positioned, and then the lateral liner portions are then removed exposing lateral adhesive portions on the covering which are applied to the neighboring skin.

It would have been obvious to have used a 3-piece liner in order to selectively uncover the central region of lerulli's dilator because as Muchin discloses it was known to position the central portion first. This would allow for easier handling of the device between the initial placement on the bridge of the nose without contacting the adhesive below the side regions. Note the teachings above of Heinecke and Faasse with regards

Art Unit: 3761

to the use of the 3-component liner system to facilitate the placement of the covering on the body.

The result of being able to only remove the central liner portion to center the device on the nose prior to removing the liner portions on the adjacent portions in order to keep the adhesive on those lateral portions covered, clean and protected before the attachment of the lateral portions to the sides of the nose would not be unexpected. One skilled in the art would recognize that providing a release liner in 3 separate portions would afford the user the ability to adhere portions of the support to the skin of the user while allowing other portions of the adhesive to stay protected until needed to be exposed

Claims 22 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muchin-'224 in view of either Heinecke-5088483 or Faasse-4744355.

Muchin discloses the invention as claimed with the exception of the release liner being in 1 piece instead of 3.

Heinecke discloses an adhesive wound covering having as shown in fig. 2 a release liner of three components- a middle component 22, and two lateral components 24. In use, the middle component 22 is first removed from the covering, the adhesive which was protected by the central liner portion is pressed against the skin, the covering can then be properly positioned and then the lateral liner sections 24 can be peeled to expose lateral adhesive sections on the covering to be applied to spaced lateral locations around the wound.

Art Unit: 3761

Faasse discloses a wound covering having a release liner with actually two (2) central portions 30 and two lateral portions 20. Again, the central portions are removed thus exposing adhesive on the covering which is applied to the skin, the covering is properly positioned, and then the lateral liner portions are then removed exposing lateral adhesive portions on the covering which are applied to the neighboring skin.

It would have been obvious to have used a 3-piece liner in order to selectively uncover the central region of Muchin's dilator because as Muchin discloses it was known to position the central portion first. This would allow for easier handling of the device between the initial placement on the bridge of the nose without contacting the adhesive below the side regions. Note the teachings above of Heinecke and Faasse with regards to the use of the 3-component liner system to facilitate the placement of the covering on the body.

The result of being able to only remove the central liner portion to center the device on the nose prior to removing the liner portions on the adjacent portions in order to keep the adhesive on those lateral portions covered, clean and protected before the attachment of the lateral portions to the sides of the nose would not be unexpected. One skilled in the art would recognize that providing a release liner in 3 separate portions would afford the user the ability to adhere portions of the support to the skin of the user while allowing other portions of the adhesive to stay protected until needed to be exposed

Page 7

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 34-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6352548.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims differ only in that the support layer has a lift member. As it is notoriously well known that nasal dilators have lift members, to have claimed the device of claim 3 with 2 lift members would have been an obvious design choice.

Response to Arguments

Applicant's arguments filed 08-18-03 have been fully considered but they are not persuasive.

The examiner has provided additional and different teachings and motivation for providing the prior art nasal dilators with a 3-piece release liner system as outlined above. Claiming an invention broader in scope than that of a patent is not patentably distinct. Therefore the fact that claim 3 of the patent includes a carrier layer not in the

Application/Control Number: 10/087,668

Art Unit: 3761

applications claim 34 is not persuasive. The additional statement as to how the 3-piece

Page 8

liner works is functional and would have been known to one skilled in the art given the

patent claim.

Allowable Subject Matter

Claims 23,24 and 27 are objected to as being dependent upon a rejected base

claim, but would be allowable if rewritten in independent form including all of the

limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Glenn K Dawson whose telephone number is 703-308-

4304. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone numbers for

the organization where this application or proceeding is assigned are 703-305-3590 for

regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the receptionist whose telephone number is 703-308-

0858.

Glenn K Dawson Primary Examiner

Art Unit 3761